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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HARRIS, ALANA M	
ART UNIT	PAPER NUMBER
1642	12

DATE MAILED: 06/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,430	FARIS ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 March 2003* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-67* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *See Continuation Sheet* .

Continuation of Attachment(s) 6). Other: Restriction Election Facsimile Transmission.

Election/Restrictions

1. The Examiner of record has changed and contact information is provided at the close of the action. The Examiner acknowledges Applicants' election (Paper number 11 received March 31, 2003) based on the previous Examiner's restriction requirement. However, upon consideration the previous election restriction requirement mailed October 25, 2002 has been vacated and new requirement is set forth below.

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-3 and 37-39, drawn to a method monitoring 158P1D7 gene products and determining status of elevated 158P1D7 mRNA, classified in class 436, subclass 63. Claims 1-3, 37 and 39 will be examined with this Group to the extent that the assay detects mRNA and utilizes a polynucleotide.

   II. Claims 1-3, 37 and 39, drawn to a method monitoring 158P1D7 gene products and determining status of elevated 158P1D7 protein expression, classified in class 436, subclass 64. Claims 1-3, 37 and 39 will be examined with this Group to the extent that the assay detects protein utilizing an antibody.

   III. Claims 4-6, 8, 25, 26, 28, 30, 31, 34 and 35, drawn to a composition comprising a substance that modulates the status of 158P1D7, wherein the substance is an antibody, classified in class 530, subclass 387.7.

Claims 4-6 will be examined with this Group to the extent that the composition includes an antibody.

IV. Claims 4, 7, 27, 29, 32, 46 and 60-66, drawn to a composition comprising a 158P1D7-related protein, classified in class 530, subclass 350. Claim 4 will be examined with this Group to the extent that the composition includes polypeptide.

V. Claims 4-6 and 9, drawn to a composition comprising a polynucleotide that encodes a single chain monoclonal antibody that binds to a 158P1D7-related protein, classified in class 536, subclass 23.53. Claims 4-6 will be examined with this Group to the extent that the composition includes a polynucleotide that encodes an antibody.

VI. Claims 4-6, 10, 36, 41-45 and 47-59, drawn to a composition that comprises a polynucleotide comprising a 158P1D7-related protein coding sequence, classified in class 530, subclass 350. Claims 4-6 will be examined with this Group to the extent they read on a polynucleotide that encodes a 158P1D7-related protein.

VII. Claims 4-6 and 11, drawn to a composition that comprises an antisense polynucleotide complementary to a polynucleotide having a 158P1D7 coding sequence, classified in class 536, subclass 24.5. Claims 4-6 will be examined with this Group to the extent that the composition includes an antisense polynucleotide.

VIII. Claims 4-6 and 12, drawn to a composition that comprises a ribozyme capable of cleaving a polynucleotide having 158P1D7, classified in class 536, subclass 24.5. Claims 4-6 will be examined with this Group to the extent that the composition includes a ribozyme.

IX. Claims 13, 14 and 20, drawn to a method of inhibiting growth of cancer cells that expresses 158P1D7 comprising administering to the cells an antibody composition, classified in class 436, subclass 512. Claim 13 will be examined with this Group to the extent the method reads on an antibody composition.

X. Claims 13, 15 and 16, drawn to a method of inhibiting growth of cancer cells that expresses 158P1D7 comprising administering to a patient a vector that comprises a polynucleotide that encodes a single chain monoclonal antibody, classified in class 435, subclass 320.1. Claim 13 will be examined with this Group to the extent the method reads on the *in vivo* administration of a polynucleotide that encodes an antibody.

XI. Claims 13 and 17, drawn to a method of inhibiting growth of cancer cells that expresses 158P1D7 comprising administering to the cells an antisense polynucleotide, classified in class 514, subclass 44. Claim 13 will be examined with this Group to the extent the method reads on utilizing an antisense polynucleotide composition.

XII. Claims 13 and 18, drawn to a method of treating a patient with cancer comprising the *in vivo* administration of a ribozyme, classified in class 514,

subclass 1. Claim 13 will be examined with this Group to the extent the method reads on the in vivo administration of a ribozyme.

XIII. Claim 19, 21-24 and 67, drawn to a method of generating a mammalian immune response comprising exposing cells to an immunogenic portion of 158P1D7-related protein that comprises at least one T cell or B cell, classified in class 435, subclass 325. Claim 19 will be examined with this Group to the extent that the method involves exposing cells to a protein.

XIV. Claims 33, drawn to a non-human transgenic animal, classified in class 800, subclass 6.

XV. Claims 40, drawn to an assay for detecting the presence of 158P1D7 mRNA in a biological sample, wherein the method comprises reverse transcription, classified in class 435, subclass 91.2.

3. The inventions are distinct, each from the other because of the following reasons:

Inventions III-VIII, XIV and I, II, IX-XIV, XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Groups III-VIII and XV are different products, whereas Groups I, II, IX-XIV and XVI are different methods.

Inventions I and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the methods of Groups I and XV, both assay for mRNA however use materially different assays.

Inventions III and II and IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody product of Group III can be used in both the *in vitro* method of Group II and the *in vivo* method of Group IX.

Inventions III and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody product of Group III can be made using a non-human transgenic animal or by a materially different process such as hybridoma technology.

Inventions V, VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions of Groups V, VI and VII are all polynucleotides, however they all encode materially distinct polypeptides.

Inventions VIII and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the ribozyme product of Group VIII can not only be used in an *in vivo* method of Group XII but in the *in vitro* method of cleaving mRNA.

Inventions IV and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group IV not only can be implemented in the *in vivo* method of Group XIII but also in an *in vitro* assay, such as Western blot analysis.

Inventions IX-XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of inhibiting the

growth of cancer cells of Groups IX-XI can be implemented using materially distinct products.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. A telephone call was made to David L. Devernoe on June 5, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is

(703) 306-5880. The examiner can normally be reached on 6:30 am to 4:00 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

ALANA HARRIS
PATENT EXAMINER

Alana M. Harris, Ph.D.
June 5, 2003